K063764
Page 1 of 2

MAY 16 2007

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Southern Spine, LLC
502 Mulberry Street, Second Floor
Macon, GA 31201
Phone: (478) 744-9992

Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

510(k) Number:

Date Prepared: December 19, 2006

Device Name and Classification:

Trade/Proprietary Name:	Southern Spine Anterior Cervical Stabilization System (SSACSS), Kwik-Fix™ Cervical System, and Kwik-Fix/TS™ Cervical System
Common Name:	Spinal intervertebral body fixation orthosis
Classification Name:	Spinal intervertebral body fixation orthosis
Product Code:	KWQ

Legally Marketed Predicate Device:

Southern Spine Anterior Cervical Stabilization System (originally called Smisson Stabilization System) - 510(k) # K021979

Device Description:

The Southern Spine Anterior Cervical Stabilization System (SSACSS) is used as a temporary construct that assists in normal healing and is not intended to replace normal body structures. The system is implanted via an anterior approach to the cervical spine. The SSACSS includes various sizes of Titanium plates with or without Tissue Shields that may be used for One-Level, Two-Level, and Three-Level anterior cervical fusion procedures. There is a selection of Titanium screws and instrumentation for implantation. The implants and delivery instrumentation are provided Non-Sterile.

Indications for Use:

The Southern Spine Anterior Cervical Stabilization System (SSACSS) is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine (C2-T1) during the development of cervical spine fusions in patients with degeneration disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

510(k) SUMMARY

Similarities and Differences to the Predicate Devices:

Similarities

The Southern Spine Anterior Cervical Stabilization System will include an additional set of plates that have Tissue Shields to cover the screws after implantation. These modified plates will have the same intended use as the predicate Southern Spine Anterior Cervical Stabilization System plates and the material and performance specifications are the same. The modified plates will also be manufactured for Southern Spine, LLC by the same manufacturer and will be supplied as a non-sterile system. The packaging and labeling (Instructions for Use, etc.) are similar except in the descriptions of specific use of the rotating Tissue Shields.

Differences

The Southern Spine Anterior Cervical Stabilization System will include a set of plates that have Tissue Shields that are rotated to cover the screws after implantation. These modified plates will have the same intended use as the predicate Southern Spine Anterior Cervical Stabilization System plates and the material and performance specifications are the same.

The Tissue Shields allow the screws to subside during the healing process and results in a dynamic system rather than a static one. Because tissue is "blocked" from growing around the screws, the screws are allowed to subside in the screw channels of the plate, and allow further bone growth to occur. With the Tissue Shield, if tissues and structures were to get in the screw space, this subsidence is hindered. The Tissue Shield protects tissue and structures (tendons, ligaments, nerves, etc) from prolapsing into the screw space. The Tissue Shield maximizes the freedom of movement for bone growth/fusion to occur.

These modifications do not affect the safety or efficacy of the Southern Spine Anterior Cervical Stabilization System. The labeling reflects the changes.

Summary of Testing:

The Southern Spine Anterior Cervical Stabilization System has the same indications for use, principles of operation, and mechanical characteristics as the predicate devices that were previously cleared for market under 510(k) # K021979. These conclusions were verified in performance / bench testing as summarized within the 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Southern Spine, Limited Liability Company
c/o Ms. Julie Stephens
Regulatory Resources Group, Incorporated
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

MAY 16 2007

Re: K063764
Trade/Device Name: Southern Spine Anterior Cervical Stabilization System
Regulation Number: 21 CFR §888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 26, 2007
Received: April 27, 2007

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

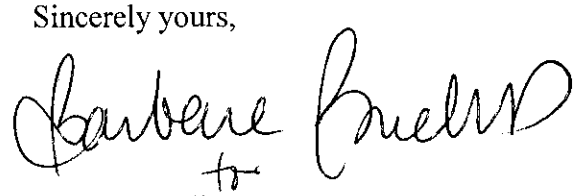
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063764

Device Name: Southern Spine Anterior Cervical Stabilization System (SSACSS)

Indications For Use:

The Southern Spine Anterior Cervical Stabilization System (SSACSS) is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine (C2-T1) during the development of cervical spine fusions in patients with degeneration disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine..

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063764